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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,113	03/15/2001	K. Roger Aoki	17006CON1	8430

7590 11/12/2002

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT PAPER NUMBER

1646

DATE MAILED: 11/12/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/812,113

Applicant(s)

AOKI ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 11-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 11-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_

### **DETAILED ACTION**

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 04, 2002 has been entered.

#### ***Response to Amendment***

2. Claims 4 and 16-19 have been amended and claims 1 and 11-12 have been cancelled as requested in the amendment of Paper No. 11, filed on September 04, 2002. Claims 1 and 11-15 are pending in the instant application.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

#### ***Claim Objections***

5. Claim 1 is objected to because of the following informalities: "and; stuttering" (line 5), should be "and stuttering", perhaps. Appropriate correction is required.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
7. Claims 1 and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ludlow et al. (New England J. of Medicine, 1992, Vol.326, No.5, pp.349-350) in view of

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Simpson (Pharmacol. Reviews, 1981, Vol.33, No.3, pp.155-188) and Jankovic et al. (New England J. of Medicine, 1991, Vol.324, No.17, pp.1186-1194).

Claims 1 and 11-15 are directed to a method of treating a patient suffering from a neuromuscular disorder or condition by administering to the patient a botulinum toxin type A until the patient experiences loss of clinical response to the administration of botulinum toxin type A, and thereafter administering a botulinum toxin type B.

Ludlow et al. teach the treatment of neuromuscular disorders such as torticollis, stuttering and oromandibular dystonia (see Table 1, page 349) by intramuscular injection of botulinum toxin type F after the patients had already been treated with botulinum toxin type A. This publication further discloses that similar protocol can be used to treat a variety of movement disorders (page 350, last paragraph). Ludlow et al. do not expressly disclose the use of botulinum toxin of type B instead of botulinum toxin type F.

Simpson reviews the pharmacological activities of the various botulinum toxin serotypes: A, B, C<sub>1</sub>, C<sub>2</sub>, D, E, F and G. The reference teaches that all of the serotypes are produced by the same species of bacterium, that all block acetylcholine release from nerve endings, and that all of the serotypes are antigenically distinct (see p.155-156). Thus, one skilled in the art would reasonably expect that administration of a botulinum toxin of any serotype would produce the same physiological effect of neuromuscular blockade and muscle weakness or paralysis. Furthermore, because the serotypes differ antigenically, antibodies developed against a first administered serotype would not be expected to block the activity of a second, subsequently administered serotype. This is consistent with publication of Ludlow et al., which teaches that

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the advantage of administering a second serotype toxin is to overcome the reduced responsiveness to the first toxin.

Jankovic et al. disclose that botulinum toxin is used for treatment of neuromuscular disorders such as muscular spasms (see Table 1 on page 1187). Jankovic et al. further submit that « [i]t is likely that patients with antibodies against botulinum toxin will respond to injections with other botulinum toxins that are immunologically distinct from type A" (page 1189, column 1).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to use a different botulinum toxin type for the treatment of neuromuscular disorders in the patient that were already treated with botulinum type A, as taught by Ludlow et al. One of ordinary skill in the art would be motivated to use any of a different serotype botulinum toxins, including B type, because teachings of Simpson and Jankovic et al. clearly indicate the benefits of such treatment.

8. It appears that principles of Res Judicata would be applicable to this rejection since it is the same issue, which was decided previously by Board of appeals in Application No.08/075,048 in the Proceedings of Appeal No. 972367.

MPEP 706.03(w) states that : Res judicata may constitute a proper ground for rejection. However, as noted below, the Court of Customs and Patent Appeals has materially restricted the use of res judicata rejections. It should be applied only when the earlier decision was a decision of the Board of Appeals or any one of the reviewing courts and when there is no opportunity for further court review of the earlier decision. The timely filing of a second application copending with an earlier application does not preclude the use of res judicata as a ground of rejection for the second application claims.

When making a rejection on res judicata, action should ordinarily be made also on the basis of prior art, especially in continuing applications. In most situations the same prior art which was relied upon in the earlier decision would again be applicable. In the following cases a rejection of a claim on the ground of res judicata was sustained where it was based on a prior adjudication, against the inventor on the same claim, a patentably nondistinct claim, or a claim involving the same issue.

In re Freeman, 30 F.3d 1459, 31 USPQ 2d 1444 (Fed. Cir. 1994).

Edgerton v. Kingland, 168 F. 2d 121, 75 USPQ 307 (D.C. Cir. 1947).

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In re Szwarc , 319 F.2d 277, 138 USPQ 208 (CCPA 1963).

In re Katz , 467 F.2d 939, 167 USPQ 487 (CCPA 1970) (prior decision by District Court).

In the following cases for various reasons, res judicata rejections were reversed.

In re Fried , 312 F.2d 930, 136 USPQ 429 (CCPA 1963) (differences in claims).

In re Szwarc , 319 F.2d 277, 138 USPQ 208 (CCPA 1963) (differences in claim).

In re Hellbaum , 371 F.2d 1022, 152 USPQ 571 (CCPA 1967) (differences in claims).

In re Herr , 377 F.2d 610, 153 USPQ 548 (CCPA 1967) (same claims, new evidence, prior decision by CCPA).

In re Kaghan , 387 F.2d 398, 156 USPQ 130 (CCPA 1967) (prior decision by Board of Appeals, final rejection on prior art withdrawn by examiner "to simplify the issue," differences in claims; holding of waiver based on language in MPEP at the time).

In re Craig , 411 F.2d 1333, 162 USPQ 157 (CCPA 1969) (Board of Appeals held second set of claims patentable over prior art).

In re Fisher , 427 F.2d 833, 166 USPQ 18 (CCPA 1970) (difference in claims).

In re Russell , 439 F.2d 1228, 169 USPQ 426 (CCPA 1971) (new evidence, rejection on prior art reversed by court).

In re Ackermann , 444 F.2d 1172, 170 USPQ 340 (CCPA 1971) (prior decision by Board of Appeals, new evidence, rejection on prior art reversed by court).

Plastic Contact Lens Co. v. Gottschalk , 484 F.2d 837, 179 USPQ 262 (D.C. Cir. 1973) (follows In re Kaghan).

### *Conclusion*

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003.

The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

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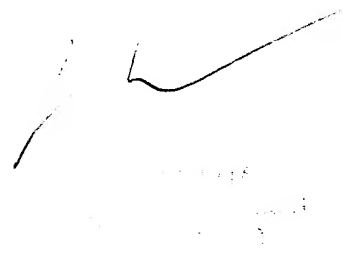
Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.  
November 7, 2002

OC

Handwritten signature and initials, possibly "OC" and "11/7/02", in the bottom right corner.